

or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

**§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.**

(a) *Identification.* A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,'" "

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," "

(iii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," "

(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices," and

(v) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components," "

(2) International Organization for Standardization's (ISO):

(i) ISO 5832-3:1996 "Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy," "

(ii) ISO 5832-4:1996 "Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy," "

(iii) ISO 5832-12:1996 "Implants for Surgery—Metallic Materials—Part 12:

Wrought Cobalt-Chromium-Molybdenum Alloy," "

(iv) ISO 5833:1992 "Implants for Surgery—Acrylic Resin Cements," "

(v) ISO 5834-2:1998 "Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms," "

(vi) ISO 6018:1987 "Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling," and

(vii) ISO 9001:1994 "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing," and

(3) American Society for Testing and Materials':

(i) F 75-92 "Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material," "

(ii) F 648-98 "Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants," "

(iii) F 799-96 "Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants," "

(iv) F 1044-95 "Test Method for Shear Testing of Porous Metal Coatings," "

(v) F 1108-97 "Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants," "

(vi) F 1147-95 "Test Method for Tension Testing of Porous Metal Coatings," "

(vii) F 1378-97 "Specification for Shoulder Prosthesis," and

(viii) F 1537-94 "Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants." "

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

**§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.**

(a) *Identification.* A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a